



2016

Stepping On: Gait Velocity and Fall Risk Assessment

Brittney Herbst
University of North Dakota

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STEPPING ON: GAIT VELOCITY AND FALL RISK ASSESSMENT

by

Brittney Herbst
Bachelor of Science in Exercise Science
University of North Dakota. 2013

A Scholarly Project

Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine

University of North Dakota

In partial of the requirements

For the degree of

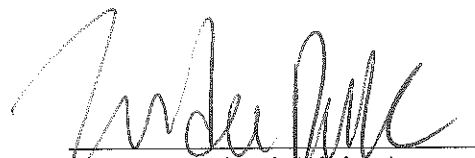
Doctor of Physical Therapy

Grand Forks, North Dakota


May

2016

This Scholarly Project, submitted by Brittney Herbst in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Faculty Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.



(Graduate School Advisor)



(Chairperson, Physical Therapy)

PERMISSION

Title Stepping On: Gait Velocity and Fall Risk Assessment

Department Physical Therapy

Degree Doctor of Physical Therapy

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Signature Betty Holt

Date 10/16/15

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ABSTRACT

Purpose: To identify fall risk and determine if the Stepping On program is effective at reducing the risk of falls in participants by increasing gait speed to greater than or equal to 1 m/s. Step and stride length were also compared to age related norms to determine if they correlated to fall risk. Gait speed of less than 1 m/s has been shown to increase the risk for falls in elderly.

Methods: Fourteen female participants over the age of 65 (mean age of 87) were recruited from a local Stepping On class conducted at an assisted living facility in order to assess gait speed. The Stepping On class included balance and strength exercises along with education on fall prevention strategies that were taught one session per week over a period of seven weeks. Gait speed, step length, and stride length were analyzed both at the first and seventh week of the class using the GAITRite walkway. Participants also filled out several surveys that were used to help with fall risk assessment and activity levels.

Results: Seven participants completed both the pre and post gait tests. Five of seven participants (71%) were able to improve their gait speed along with step and stride length, with four (57%) increasing gait speed by greater than .05 m/s which has been established as the MCID. The average gait speed at Week 7 was 0.69 m/s which was less than the cut off measure for being at risk for falls is 1.0 m/s.

Conclusion: Further research needs to be conducted to see if members of an assisted living facility can decrease risk of falls by increasing their gait speed after taking part in the Stepping On program. Possible limitations to this study include increased age of participants, exercise compliance, no incorporated walking program and multiple other tests performed on the same day. Future research could look at the relationship between balance confidence and gait speed or TUG scores along with testing at the three month follow-up session. Other correlations could be looked at between the 30 Second Sit to Stand Test, the Cognitive TUG, or the 4 Stage Balance Test.

CHAPTER I

INTRODUCTION

Falls are a major health concern in the elderly population. It has been shown that more than 50% of falls in those over the age of 65 occur during some form of locomotion.¹ A decline in gait speed of .15 meters per second or larger from normal speed has been found to be predictive of falls with an incidence rate ratio of 1.86.² A systematic review of usual gait speed discovered that gait velocity of less than 1 m/s for a 6 meter course was found to be a predictor of persistent lower extremity limitation with a relative risk value of 2.2. Normative gait speed declines each decade for individuals over the age of 70 and ranges from 0.98 to 1.16 meters per second.³

Decreased gait speed and other gait parameters can be influenced by many different factors that occur with aging including increased muscle weakness, balance impairments, decreased flexibility, and variability in walking patterns which can influence the ability to execute ADL's. Gait speed and TUG scores were compared with the ability to perform ADL's and IADL's in those age 65 and older, the study observed that decreased gait speed and TUG scores were correlated with increased disability when performing ADL's and IADL's.⁵⁻⁶

Stepping On has been shown to reduce the risk of falls in the elderly by 31%,⁴ utilizing exercise and education over a seven week course. Stepping On is a multifactorial community program that meets one time per week for seven weeks aimed at decreasing

the incidence of falls in the elderly population. Mobility, strengthening and balance exercises are some of the focuses of the Stepping On class. Individuals over the age of 70 are found to have changes in gait parameters such as decreased gait speed and stride length during ambulation that can be attributed to balance impairments and decreased strength.⁴ Other topics of the program include moving safely, home hazards, vision, community safety, proper footwear, medication management, better sleep, and moving in the community. A variety of experts in the community including physical therapists educate participants on the included topics and a home visit is offered if help with home modification is needed.

Along with muscle weakness and balance impairments, risk of falling can also be affected by factors such as being indoors or outdoors due to changes in surfaces. A nonlinear relationship was found between gait speed and fall risk based on environment by Quach et al². The study was completed with adults older than 65, over an 18 month period, and individuals with a gait speed slower than 1 m/s had an increased fall risk while indoors, and a gait velocity above 1.30 m/s was shown to increase fall risk outdoors. Fall locations were based on self-reports of where the participant's falls occurred. The small meaningful change for gait speed was found to be .05 m/s.¹ Step length has also been researched as a factor affecting fall risk in the elderly population. Slowing of gait speed is known to increase risk for falls, but one study has shown that if a slowing gait speed is coupled with decreased step length this could offset the fall risk.⁷ If gait speed is increased without step length this could cause increased risk of falling. Stride length (distance from heel strike of one side to heel strike on the same side) has also been found to be associated with increased risk of falling. In one study stride length

and gait speed were compared in older adults that were grouped based on their fear of falling and reported activity restriction.⁸ It was found that the groups who were fearful of falling had significantly slower gait speed and stride lengths compared to the group that was not afraid of falling.

Gait velocity and other gait parameters have been shown to change over time due to physiologic and flexibility changes with increased age.⁹ A study performed on able bodied older adults (age 70-89) was conducted for the Mayo Clinic in order to determine normative data for gait parameters.³ The GAITRite was used to find normative data on those over the age of 70 by averaging two walking trials for each subject with one meter before and after the walkway. Subjects were instructed to walk at their normal pace and were not allowed to use any gait aids while ambulating. The results of normative data from the study are presented in Table 1.⁴

The purpose of this study is to determine if the Stepping On program can decrease the risk of falling by improving gait speed. A speed of 1 m/s will be used for categorizing risk of falling however it has been shown that improving gait speed by just 0.1 m/s can predict improved health status.¹⁸ For this research; gait speed, step, and stride length will be measured in order to determine if the Stepping On program can decrease the risk of falls by influencing the chosen gait parameters. This study will also address if using the GAITRite to analyze gait speed is an easy and reliable tool to assess fall risk in the future.

Table 1. Normative Gait Parameters

Parameter	Men N = 108				Women N = 108			
	70-74 N = 27	75-79 N = 30	80-84 N = 37	85+ N = 14	70-74 N = 33	75-79 N = 77	80-84 N = 43	85+ N = 33
Gait speed (cm/s)	117 ± 16	122 ± 15	112 ± 17	101 ± 22	116 ± 20	112 ± 17	101 ± 15	98 ± 20
Step length (cm)	69 ± 8	68 ± 7	65 ± 8	59 ± 10	61 ± 9	59 ± 7	55 ± 7	54 ± 9
Stride length (cm)	139 ± 14	137 ± 12	131 ± 17	119 ± 21	123 ± 17	118 ± 15	111 ± 14	109 ± 18

Adapted from Hollman et al 2012³

CHAPTER II

METHODS

Subjects

Participants were recruited from a local assisted living facility to take part in the Stepping On program. Fourteen female participants initially agreed to take part in this study although only seven complete both pre and post testing with the GAITRite. Four participants dropped out of the program, one due to medical leave, and the other three were uninterested in coming back after the first two weeks. All agreeing to take part in the study signed consent forms prior to data collection (see Appendix A for consent forms). The study was approved by the IRB prior to participants being recruited (see Appendix B for IRB forms). This Stepping On class was older than a typical class (mean age of 87 years old for this study, but all participants lived independently and were able to ambulate at least 200 feet making them eligible to participate in the class, Clemson et al⁴ reported an average age of 78 years old for their study. Only three participants ambulated with no assistive device, while the remaining walkers or wheelchairs for their primary mode of transportation (see Table 2 for demographics). All participants also filled out fall risk and demographic surveys in order to provide additional information for the effectiveness of the Stepping On program (See Appendix C for Surveys).

Table 2. Demographics of Participants at Week 1

Subject #	Age	Type of Assistive Device Used	# of Falls Last Year	# of Fall Risk on UND Survey	Worry About Falling	Vision Issues/ Type	> 4 Meds	Minimally Active > 30 min/day	LE Sensation Deficits	Med Hx
1	92	None	0	3/11	No/Yes	Yes; not specified	Yes	Yes	No	
2	92	WW/WC	2	5/10	Yes	No	Yes	-	Yes	R knee pain
3	89	Manual WC/FWW	2	6/11	Yes	Yes; glasses, macular degeneration	No	No	Yes	L ankle surgery; Dizzy
4	87	FWW	0	4/11	No	Yes; not specified	Yes	Yes	No	Bilat TKA
5	94	4WW longer distances	0	1/11	No	Yes; legally blind, bifocals	No	Yes	No	
6	80	None	0	3/11	No	Yes; deficits	Yes	Yes	Yes-knee	
7	84	FWW	6-7	6/11	Yes	Yes; macular degeneration, glaucoma	Yes	No	No	
8	85	SEC	0	6/11	No	Yes; glasses	Yes	No	No	
9	80	None	2	8/11		Yes; glasses	Yes	No	Yes	L knee pain
10	87	FWW	0	3/11	No	No	Yes	No	No	R hip pain
11	84	FWW	2	6/11	Yes	Yes; macular degeneration	Yes	Yes	Yes-knee	R rotator cuff tear
12	89	4WW	Yes ?#	2/11	No/Yes	Yes; glasses	No	Yes	No	
13	90	4WW	0	5/11	No	Yes; glaucoma	No	No	Yes	R TKA; OA L knee
14	89	Power WC/4W	Yes ?#	NT	Yes					

Instrumentation

The GAITRite system (see Figure 1) is a portable computerized walkway that has embedded pressure sensors that allow for quick and reliable analysis of spatiotemporal gait parameters. An example of the Gait analysis measure of the GAITRite is found in Appendix D.



Figure 1. GAITRite Walkway

The GAITRite¹⁰⁻¹³ has been found to have concurrent validity and reliability by several different studies. Blinney et al¹⁰ compared the GAITRite with the Clinical Stride Analyzer and found speed, cadence, and stride length to have an interclass correlation coefficient (ICC) of 0.99 after averaging the results of three trials. Test-retest reliability was also found by Van Uden et al¹¹ who retested 21 subjects after one week, averaged the results of eight trials each time. They found that the subjects' comfortable walking speed had excellent test-retest reliability with an ICC value of 0.92 or higher for all parameters except for base of support. Subjects were given two meters before and after the walkway in order to allow for acceleration and deceleration. The GAITRite was also found to be reliable for both older and younger adults in a study by Menz et al¹² comparing 30 young subjects (age 22-40) and 31 community dwelling older adults (age 76-87). They averaged the results of three trials and had subjects walk two meters before and after the walkway to allow for acceleration and deceleration. This study found that the test-retest reliability for walking speed, cadence, and step length ranged from .82-.91, compared with younger subjects having an ICC of .83-.94 for all gait parameters. The GAITRite is an easy way to evaluate all gait parameters, but due to its increased expense, it is not available for use in all clinics.

A more economical option would be to calculate gait speed with a stopwatch. Youdas et al¹³ compared the GAITRite with the use of a stopwatch, and found with three trials averaged, the intra-tester reliability with the stopwatch was found to have an ICC of .88 for gait speed measurements. Reliability was found to be less for stride length and cadence compared to the GAITRite. If the GAITRite is not available due to cost, the 10

Meter Walk Test can be used in place of the GAITRite. Peters et al¹⁴ assessed the reliability and validity of the 4 Meter and 10 Meter Walk Test for healthy older adults. Subjects were 65 and older and were instructed to walk at a comfortable speed for a 4 Meter Test (two meters before and after the measured distances) and the 10 Meter Test (five meters before and after). Each test was performed three times and participants were allowed to use assistive devices if needed. An automatic timer was used along with a stopwatch recording, with time starting when the participants lead leg (or assistive device) crossed the first marking for the test, and time was stopping when the lead leg crossed the next marker. Both the 4 and 10 Meter tests had excellent test-retest reliability with ICC of .96-.98. Reliability was found to be similar for both the automatic timer and the stopwatch method with standard error of measurement value between .004 and .008 m/s. The 10 Meter Walk Test was found to have a higher validity (95% limits from -.002 to .002m/s) between the stopwatch and automatic timer compared to the 4 Meter Walk Test (95% limits from -.05-.05 m/s). They concluded that the 10-Meter Walk Test is the most valid and reliable test for older adults and a stopwatch can provide results similar to those performed with an automatic timer.

Procedure

In order to allow for proper acceleration and deceleration for this study, a summary of research conducted with the GAITRite shows that marking off one-two meters before and after the walkway will give the most accurate results in order to account for acceleration and deceleration. Subjects reported their age, gender, and height, which were entered into the computer software. Subjects were instructed to walk

at a comfortable speed for two trials. The two trials were averaged in order to allow for greater accuracy without tiring the participants.¹⁰⁻¹³ Subjects had a spotter walking behind them if the researcher felt they required one. Assistive devices were allowed to be used if participants used them for their everyday ambulation. The second trial was conducted as soon as participants felt they were ready to ambulate again.

Data was collected on the first and seventh weeks of the Stepping On program. Gait velocity, step, and stride length were recorded from the GAITRite software analysis. An average of two trials was used for each subject with the exception of one trial that was lost due to computer error. Participants also performed 4 other physical tests (TUG, Cognitive TUG, 4 Stage Balance Tests, and the 30 Second Chair Stand Test) along with the Activities-Specific Balance Confidence Scale questionnaire during both testing sessions. All of the tests were performed in a random fashion to control for error. Data was analyzed by the number of participants that had a change in gait velocity, step, or stride length. Change was reported as a percentage of the total participants.

CHAPTER III

RESULTS

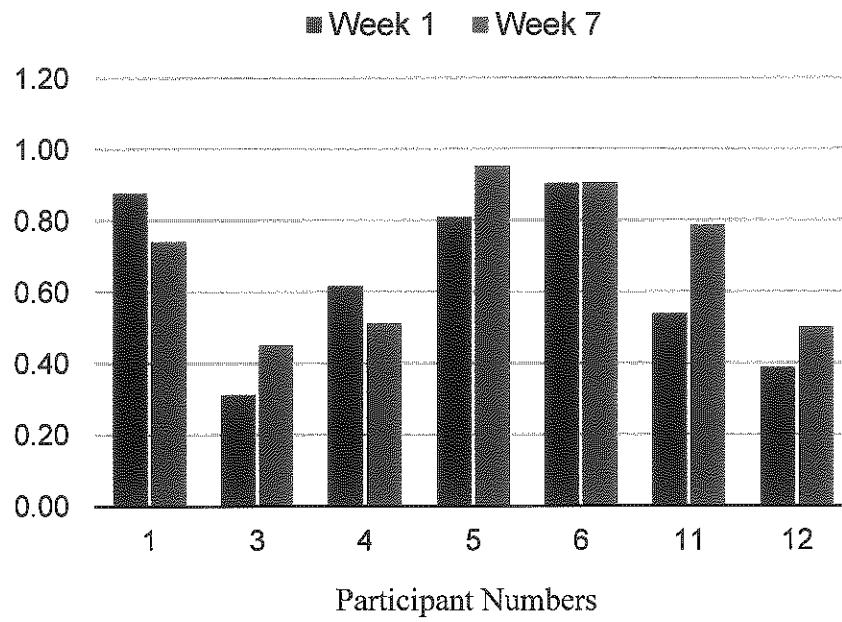
Five of the seven participants that completed both the pre and post tests were found to increase their gait speeds between the two testing periods. Four participants of seven (57%) increased their gait velocity by greater than 0.05 m/s which has been shown to be the small meaningful change for gait speed.¹ Four participants were able to improve gait speeds by greater than 0.10 m/s which has been shown to improve health status.¹⁸ Two subjects only completed one of the two testing periods due to absence on one of the testing days, therefore their results were unable to be analyzed for improvement. Results for each participant are reported in Table 3, all data was averaged from two trials unless otherwise noted. Those who did not use an assistive device (AD) for everyday ambulation had increased gait speeds compared with the remaining subjects. All participants had a gait speed less than 1 m/s at the pre and post program testing (average speed was 0.69 m/s), placing them at an increased risk for falls. Five of the seven participants had a gait speed 0.15 m/s or more less than age predicted normative values of 0.98-1.12 m/s. According to a study mentioned previously this means they are 1.86 times more likely to fall.² The five that had decreased age normative gait speeds also reported that they were more fearful of falling. Changes in participants gait speeds are shown in Table 4.

Five participants who completed both testing days were able to increase step and stride length between Week 1 and Week 7 of testing. All participants had decreased stride and step length (except for one participant who had normal step length) compared to normative age data from Table 1 (average stride length for this age group is 111 cm). Decreased step length can be an adaptation for fear of falling and slowing of gait speed, the slow gait speeds found in this study correlate with the decreased step and stride length. Gait speed seemed to be correlated with fall risk as those with the slowest gait velocity tended to have a greater number of CDC fall risk factors (see Table 2). Participants with a gait speed of greater than .70 had a score of 6/11 or less on our fall risk survey putting them at an increased risk of falling. Although participants did not improve gait speeds enough to decrease their risk of falls, there were no falls by any participant during the seven week Stepping On program. Three of the seven participants (42%) reported having one or more falls in the last year before completing the program. Participants are invited to a three-month recheck session in order to assess how their exercises are going. Checking balance during this time period may allow for greater results.

Table 3. Week 1 and Week 7 GAITRite Results

Participant	Age	Gait Speed Week 1 (m/s)	Step Length Left/Right Week 1 (cm)	Stride Length Left/Right Week 1 (cm)	Fall Risk Week 1 (<1m/s)	AD Used	Gait Speed Week 7 (m/s)	Step Length Left/Right Week 7 (cm)	Stride Length Left/Right (cm)	Fall Risk Week 7 (<1m/s)
1	92	0.877	L= 44.60 R= 42.46	L= 86.68 R= 87.75	Yes	None	0.741	L= 40.45 R= 39.66	L= 81.03 R= 80.11	Yes
2	92	0.540	L=29.74 R=34.90	L= 63.97 R= 65.18	Yes	WW	-	-	-	-
3	89	0.313	L=31.79 R=32.79	L= 64.76 R= 64.08	Yes	WW	0.451	L=37.03 R=38.23	L= 74.92 R= 75.55	Yes
4	87	0.617	L=37.84 R=37.60 (one trial)	L= 75.39 R= 75.94 (one trial)	Yes	WW	0.512	L=36.63 R=34.45	L= 71.41 R= 71.32	Yes
5	94	0.809	L=37.91 R=42.69	L= 79.36 R= 81.89	Yes	None	0.953	L=40.57 R=46.15	L= 86.82 R= 87.54	Yes
6	80	0.905	L=53.89 R=53.90	L=108.87 R=107.57	Yes	None	0.906	L=53.29 R=55.46	L=109.77 R=108.83	Yes
7	84	0.540	L=38.42 R=29.94	L= 68.89 R= 68.11	Yes	WW	-	-	-	-
8	85	0.524	L=35.12 R=30.11	L= 65.52 R= 65.43	Yes		-	-	-	-
9	80	0.622	L=40.71 R=47.92	L= 88.95 R= 88.07	Yes		-	-	-	-
10	87	0.970	L=45.31 R=50.99	L= 97.96 R= 96.48	Yes		-	-	-	-
11	84	0.539	L=45.31 R=50.99	L= 95.27 R= 95.43	Yes	WW	0.786	L=49.30 R=49.74	L= 99.15 R= 99.85	Yes
12	89	0.388	L=15.65 R=19.48	L= 35.93 R= 35.52	Yes	WW	0.501	L=20.16 R=29.78	L= 50.71 R= 50.29	Yes
13	90	-	-	-	-		0.555	L=40.71 R=41.85	L= 82.62 R= 82.41	Yes
14	89	-	-	-	-	WW	0.435	L=33.27 R=36.59	L= 70.97 R= 69.67	Yes

Table 4: Change In Gait Velocity (m/s) (<1m/s is fall risk)



CHAPTER IV:

DISCUSSION/CONCLUSION

Discussion

The Stepping On program was found to be successful in reducing fall risk in community-dwelling elderly by 31% as found by Clemson et al.⁴ This research group was not a typical community dwelling class as is typical for other Stepping On programs, the participants were able to live independently but they did live in an assisted living facility. Testing results showed that five of the seven participants (71%) who completed both testing sessions were able to improve their gait speeds along with step and stride length (4 improving greater than .05 m/s) following the Stepping On program. Based on gait velocity results at Week 7, four of the seven participants (57%) had a gait speed greater than 0.67 m/s which has been shown to be the speed required for completing self-care activities.¹⁹

Although 71% of participants were able to increase their gait parameters measure (gait velocity, step, and stride length) all remained below 1 m/s for gait velocity which is being used as the cut off for fall risk in this study. All seven participants met the criteria of being a limited community ambulator; which is classified as a gait velocity of 0.4-0.8 m/s.²⁰ Two participants had a gait velocity greater than 0.8 m/s putting them in the community ambulatory category. Because participants in this study lived in an assisted

living facility many used an assistive device (four of the seven participants at week 7) which causes a decrease in gait velocity.

There are several reasons for lack of significant decrease in fall risk (gait velocity of >1 m/s) for this study. The Stepping On program does not place an emphasis on gait speed or on an ambulation program during the class. The time frame of the Stepping On class (1x per week for 7 weeks) and testing dates (Week 1 and Week 7 of the program) may not have been long enough to show significant improvements. Another preventative exercise study found that after one year of completing balance and strength exercises, a group of pre frail elderly women (average age of 78) were able to significantly improve their time for a five meter walk test and the TUG (Timed Up and Go test).¹⁵ Kisner and Colby report that a minimum of 50 hours of balance training is needed in order to improve balance.¹⁶ Having an additional exercise time or encouraging a walking program separate of the Stepping On program could help improve balance further along with testing at a later date.

Performing five different physical tests to assess falls may not be appropriate for future Stepping On programs to assess fall risk. Gait speed is not addressed specifically in the Stepping On program, and many facilities will not have access to a GAITRite. One study has found that performing the TUG can show fall risk reduction on its own without any other physical testing measures.¹⁷ Gait speed is an important measure of functional capacity but may not be necessary to address fall risk for the Stepping On program.

Limitations

This study had several limitations to it; there were a very small number of participants which made statistical analysis difficult. The average age of the participants (mean age of 87) was higher than a typical Stepping On class (mean age of 78), and most of the participants (57% reported on fall risk survey) were at a very high risk of falls prior to beginning the program. Nine participants reported using an assistive device for ambulation and two participants out of 14 reported using a wheelchair for their primary mode of mobility. Due to increased average age and use of assistive devices, the participants had difficulty performing many of the exercises and required a lot of individualized assistance; many reported that they were fearful of performing exercises on their own. Fear of completing exercises was one reason why participants were not compliant with completing the exercises as instructed. Other testing measures were performed along with the GAITRite (30 Second Chair Stand Test, Four Stage Balance Test, TUG, and the Cognitive TUG) could have affected gait speeds or performance on other tests due to fatigue.

Conclusion

The Stepping On program has been found to decrease fall risk in the elderly population.⁴ The group studied for this research was older than the typical Stepping On class, (mean age of 87 versus 78) despite the increased age participants were still found to increase their gait seed and stride length during the seven week program. There were no falls reported by any participant for the duration of the program. Having group exercise sessions during other days of the week other than the Stepping On class could help to

improve exercise compliance. A walking program could be recommended during the Stepping On program in order to improve gait speeds along with balance improvements. Performing five different physical tests is not appropriate or efficient for this age group. Gait speed may be related to fear of falling; future research could look at analyzing the ABC scores compared with gait speed, TUG, Cognitive TUG, or 4 Stage Balance Test results. Other studies could look at testing participants at the three month recheck to determine if balance has improved more over time.

APPENDIX A

INFORMED CONSENT

TITLE: The Effectiveness of the "Stepping On" Program for Reducing the Incidence of Falls in the Elderly

PROJECT DIRECTOR: Meridee Danks and Beverly Johnson

PHONE # 701-777-2831

DEPARTMENT: Physical Therapy

STATEMENT OF RESEARCH

A person who is to participate in the research must give his or her informed consent to such participation. This consent must be based on an understanding of the nature and risks of the research. This document provides information that is important for this understanding. Research projects include only subjects who choose to take part. Please take your time in making your decision as to whether to participate. If you have questions at any time, please ask.

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to be in a research study that will look at the effectiveness of education and exercise in reducing falls. You have been identified as a possible subject as you are presently participating in the "Stepping On" program. The purpose of this research study is to test whether the Stepping On program is effective in reducing falls in older people living at home. Participants need to be 65 or older, live in on their own, and be able to walk independently in the community.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 10-12 people at each site will take part in this study being performed by University of North Dakota Department of Physical Therapy.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in the study will last the same length of time you will be in the Stepping On program (7 weeks with a 3 & 6-month follow-up). The assessment times will be at the same days as when you will be attending your Stepping On program. Each visit will take about 20 minutes during the Day 1, Day 7, 3-month & 6-month recheck of the Stepping On program.

Date _____
Subject Initials: _____

WHAT WILL HAPPEN DURING THIS STUDY?

Assessments will occur at Week 1 and 7 sessions and then at 3 month booster session and at 6 month recheck at the same site. Assessment will include the following:

1. Baseline Questionnaire and Fall Risk Survey - are filled out as part of the Stepping On program. Questionnaire is to gather demographic, mobility and fall information. You are free to skip any questions that you prefer not to answer. Time to complete is ~10 minutes.

Additional test performed (beyond Stepping On gathered information), include:

2. Activities-specific Balance Confidence (ABC) Scale - subject rates level of confidence in doing everyday activities with out falling using a 0 – 100% scale (0 = no confidence to 100 = completely confident). Total score is sum of 16 individual activity scores, which is than averaged, the higher the score the less concerns the subject has about falling. Time to complete is less than 5 minutes.

3. Sit to Stand Test (STS) - the subject will be asked to go from a sit to stand for 30 seconds. The number of repetitions will be completed in 30 sec and the length of time to complete the first 5 sit to stands will be recorded. This is an objective measurement of strength and balance. Time to complete ~ 3 minutes.

4. Timed Up and Go Test (TUG) - the test requires that subjects stand up from a chair, walk 10 ft, turn around, and return. The time to complete the activity is recorded. A second trial will be performed with the subject performing a cognitive task (i.e. subtracting by 3s or spelling words) while walking. A safety belt will be used when performing the assessment. Time to complete is 1 minute. This is an objective measure of balance in an activity of daily function. If available, the GAITRite electronic walkway may be used to allow the researchers to gather greater data on subjects walking parameters during the 10 meter walk.

5. Four-Test Balance Scale – This is a four part balance test, each part progressively challenges a person balance. The subject first will try to balance for 10 seconds with feet together, then with feet together but one slightly ahead of the other, progressing to one foot in front of the other (heel-toe) and lastly, the subject stands on one leg for up to 30 seconds with eyes open. If subject is unable to stand for the allotted time for any part the test will be stopped. A safety belt will be used during this assessment. Time to complete is 3-5 minutes. This is an objective measure of balance and strength.

6. Fall and Activity Survey and Stepping On Participation Evaluation - each subject will be given the 2 survey's following the completion of Stepping On session at Week 7, at 3-month Booster session and at the 6 months recheck to record any falls that have occurred and to monitor follow through of assigned strength and balance exercises. Fall is defined as an event that results in a person unintentionally coming to rest on the ground, floor, or

Date _____
Subject Initials: _____

other lower level. (Buchner) If a subject is unable to attend the Booster session and/or at the 6-month recheck they will be contacted by phone or mail in regards to the survey.

WHAT ARE THE RISKS OF THE STUDY?

There may be some risk from being in this study, mainly with the potential to lose your balance. This risk will be minimized by use of safety precautions. For each physical balance assessment a safety belt and spotter will be used to prevent any falls. You can decide not to perform any assessment that you do not feel comfortable/safe performing.

WHAT ARE THE BENEFITS OF THIS STUDY?

You benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because it may help identify benefits of prevention education and exercise on falls in the elderly population. You may benefit by knowing your balance strengths and weakness that will be identified by the assessment scores.

ALTERNATIVES TO PARTICIPATING IN THIS STUDY

You can decide to participant only in the Stepping On program and not in the research study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study. Nor will you be paid for being in this research study.

WHO IS FUNDING THE STUDY?

The University of North Dakota and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.

CONFIDENTIALITY

The records of this study will be kept private to the extent permitted by law. In any report about this study that might be published, you will not be identified. Your study record may be reviewed by Government agencies, the UND Research Development and Compliance office, and the University of North Dakota Institutional Review Board Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of assigning you an identification number that will be used instead of your name on any data that is kept. Your signed consent form and your data will be stored separately in a locked room. Only the researchers will have access to any identifiable information. If we write a report or article about

Date _____
Subject Initials: _____

this study, we will describe the study results in a summarized manner so that you cannot be identified.

IS THIS STUDY VOLUNTARY?

Your participation is voluntary. You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your current or future relations with the University of North Dakota or the Stepping On program

CONTACTS AND QUESTIONS?

The researchers conducting this study are Meridee Danks and Beverly Johnson. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact **Meridee Danks or Beverly Johnson at 701-777-2831** during the day.

If you have questions regarding your rights as a research subject, or if you have any concerns or complaints about the research, you may contact the **University of North Dakota Institutional Review Board at (701) 777-4279**. Please call this number if you cannot reach research staff, or you wish to talk with someone else.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subjects Name: (Print) _____

Signature of Subject

Date

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative.

Signature of Person Who Obtained Consent

Date

Date _____
Subject Initials: _____

APPENDIX B

Institutional Review Board

Twamley Hall, Room 106
264 Centennial Drive Stop 7134
Grand Forks, ND 58202-7134
Phone: 701.777.4279
Fax: 701.777.6708

March 13, 2015

Principal Investigator:	Meridee Danks, D.P.T. and Beverly Johnson, PT, DSc, GCS
Project Title:	The Effectiveness of the "Stepping On" Program for Reducing the Incidence of Falls in the Elderly
IRB Project Number:	IRB-201209-047
Project Review Level:	Expedited 4, 7
Date of IRB Approval:	03/12/2015
Expiration Date of This Approval:	06/24/2015
Consent Form Approval Date:	03/12/2015

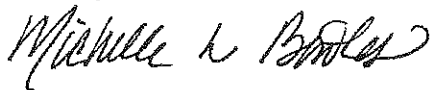
The Protocol Change Form and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the University of North Dakota Institutional Review Board.

Attached is your revised consent form that has been stamped with the UND IRB approval and expiration dates. Please maintain this original on file. **You must use this original, stamped consent form to make copies for participant enrollment. No other consent form should be used.** It must be signed by each participant prior to initiation of any research procedures. In addition, each participant must be given a copy of the consent form.

You have approval for this project through the above-listed expiration date. When this research is completed, please submit a termination form to the IRB. If the research will last longer than one year, an annual review and progress report must be submitted to the IRB prior to the submission deadline to ensure adequate time for IRB review.

The forms to assist you in filing your project termination, annual review and progress report, adverse event/unanticipated problem, protocol change, etc. may be accessed on the IRB website:
<http://und.edu/research/resources/human-subjects/>

Sincerely,



Michelle L. Bowles, M.P.A., CIP
IRB Coordinator

MLB/jle

Enclosures

Cc: Chair, Physical Therapy

University of North Dakota Human Subjects Review Form

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University's policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the "IRB Checklist" for additional guidance.

Please provide the information requested below. Handwritten forms are not accepted – responses must be typed on the form.

Principal Investigator: Meridee Danks and Beverly Johnson

Telephone: 777-3861

E-mail Address: meridee.danks@med.und.edu

Complete Mailing Address: 501 North Columbia Road, Stop 9037, Grand Forks, ND 58202-9037

School/College: UNDSMHS

Department: Physical Therapy

Student Adviser (if applicable): _____

Telephone: _____

E-mail Address: _____

Address or Box #: _____

School/College: _____

Department: _____

Project Title: The Effectiveness of the "Stepping On" Program for Reducing the Incidence of Falls in the Elderly

Proposed Project Dates: Beginning Date: 9-12-2012

Completion Date: ongoing

(Including data analysis)

Funding agencies supporting this research: NA

Did the contract with the funding entity go through UND Grants and Contracts Administration? ☐ YES or ☒ NO
Attach a copy of the contract. Do not include any budgetary information. The IRB will not be able to review the study without a copy of the contract with the funding agency.

☐ YES or ☐ NO Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

☒ YES or ☐ NO Will any research participants be obtained from another organization outside the University of North Dakota (e.g., hospitals, schools, public agencies, American Indian tribes/reservations)?

☒ YES or ☐ NO Will any data be collected at or obtained from another organization outside the University of North Dakota?

If yes to either of the previous two questions, list all organizations:

Holy Family Church, Northwood Senior Center, Grand Forks Senior Center and Calvary Lutheran Church

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands its involvement and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on organizational letterhead.

Revised 04/02/12

Does any external site where the research will be conducted have its own IRB? ☐ YES ☒ NO ☐ N/A

If yes, does the external site plan to rely on UND's IRB for approval of this study? ☐ YES ☐ NO ☐ N/A
(If yes, contact the UND IRB at 701 777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

_____	Date submitted: _____	Status: <input type="checkbox"/> Approved <input type="checkbox"/> Pending
_____	Date submitted: _____	Status: <input type="checkbox"/> Approved <input type="checkbox"/> Pending

(include the name and address of the IRB, contact person at the IRB, and a phone number for that person)

Type of Project: Check "Yes" or "No" for each of the following.

- | | | | |
|--|---|--|---------------------------------------|
| <input type="checkbox"/> YES or <input type="checkbox"/> NO | New Project | <input type="checkbox"/> YES or <input checked="" type="checkbox"/> NO | Dissertation/Thesis/Independent Study |
| <input checked="" type="checkbox"/> YES or <input type="checkbox"/> NO | Continuation/Renewal | <input type="checkbox"/> YES or <input checked="" type="checkbox"/> NO | Student Research Project |
| <input checked="" type="checkbox"/> YES or <input type="checkbox"/> NO | Is this a Protocol Change for previously approved project? If yes, submit a signed copy of this form with the changes bolded or highlighted. | | |
| <input type="checkbox"/> YES or <input checked="" type="checkbox"/> NO | Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form. | | |
| <input type="checkbox"/> YES or <input checked="" type="checkbox"/> NO | Does your project include Genetic Research? | | |

Subject Classification: This study will involve subjects who are in the following special populations: Check all that apply.

- | | |
|--|---|
| <input type="checkbox"/> Children (< 18 years) | <input type="checkbox"/> UND Students |
| <input type="checkbox"/> Prisoners | <input type="checkbox"/> Pregnant Women/Fetuses |
| <input type="checkbox"/> Cognitively impaired persons or persons unable to consent | |
| <input type="checkbox"/> Other _____ | |

Please use appropriate checklist when children, prisoners, pregnant women, or people who are unable to consent will be involved in the research.

This study will involve: Check all that apply.

- | | |
|---|--|
| <input type="checkbox"/> Deception (Attach Waiver or Alteration of Informed Consent Requirements) | <input type="checkbox"/> Stem Cells |
| <input type="checkbox"/> Radiation | <input type="checkbox"/> Discarded Tissue |
| <input type="checkbox"/> New Drugs (IND) IND # _____ Attach Approval | <input type="checkbox"/> Fetal Tissue |
| <input type="checkbox"/> Investigational Device Exemption (IDE) # _____ Attach Approval | <input type="checkbox"/> Human Blood or Fluids |
| <input type="checkbox"/> Non-approved Use of Drug(s) | <input type="checkbox"/> Other _____ |
| <input checked="" type="checkbox"/> None of the above will be involved in this study | |

I. Project Overview

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

Falls are a major concern in the elderly population. Falls can lead to impairments, functional limitations and disabilities. The North Dakota Department of Health, Division of Injury Prevention and Control has initiated the Stepping On program in several communities across North Dakota. The Stepping On program is, an established multifaceted community-based program using small-group based learning, designed to improve fall self-efficacy, encourage behavioral change, and to reduce falls. Two-hour sessions are conducted weekly for 7 weeks with a follow-up home visit and a 3 month booster session. The aim of this study is to test whether the Stepping On program is effective in reducing falls in elderly people living at home.

Revised 04/02/12

II. Protocol Description

Please provide a thorough description of the procedures to be used by addressing the instructions under each of the following categories.

1. Subject Selection.

- a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects. Subjects will be recruited from participant in the Stepping On program by word of mouth at Holy Family Church, Northwood Senior Center, Grand Forks Senior Center and Calvary Lutheran Church. The Stepping On program is being set-up at these locations.
- b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the "Subject Classification" section above. Subjects need to be attendees of the Stepping On program which is designed for individuals who are 65 or older and living in his/her own home and able to walk independently outside their home.
- c) Describe your exclusionary criteria and provide a rationale for excluding subject categories. Exclusion criteria includes any cognitive problems associated with dementia and being homebound (unable to independently leave home).
- d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects. The goals recruit approx 12 subjects at each site (Holy Family, Northwood, Grand Forks Senior Centers and Calvary Lutheran Church) to participate in the research study. The Stepping On program recommends limiting the number of participants to no more than 15 for the 7-week program.
- e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.
Only 10-15 people will be attending the Stepping On program at each site so this will limit the number.

2. Description of Methodology.

- a) Describe the procedures used to obtain informed consent. Participants of the Stepping On program will be asked if they would like to be part of this study on the introduction day of the program. If they are interested they will be given an informed consent form to review. Questions will be addressed and if willing to participate signatures will be obtained. Each volunteer will be given a copy of the consent form.
- b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research. Holy Family Church in Grand Forks, ND, Northwood Senoir Center in Northwood, ND, Grand Forks Senior Center and Calvary Lutheran Church in Grand Forks, ND.
- c) Indicate who will carry out the research procedures. Meridee Danks and Bev Johnson, physical therapists from UND physical therapy department; UND-PT students will be assisting as needed.
- d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them. Assessments will occur at Weeks 1 and 7 and then at 3 month booster session and at 6 months post Stepping On program recheck. Assessment will include the following:
 1. Baseline Questionnaire and Fall Risk Survey - are filled out as part of the Stepping On program. Questionnaire is to gather demographic, mobility and falls information. Time to complete is ~10 minutes.

Revised 04/02/12

Additional test performed (beyond Stepping On gathered information)

2. Activities-specific Balance Confidence (ABC) Scale - subject rates level of confidence in doing everyday activities with out falling using a 0 – 100% scale (0 = no confidence to 100 = completely confident). Total score is sum of 16 individual activity scores, which is than averaged, the higher the score the less concerns the subject has about falling. Time to complete is less than 5 minutes.
 3. Sit to Stand Test (STS) - the subject will be asked to go from a sit to stand for 30 seconds. The number of repetitions will be completed in 30 sec and the length of time to complete the first 5 sit to stands will be recorded. This is an objective measurement of strength and balance. Time to complete ~ 3 minutes.
 4. Timed Up and Go Test (TUG) - the test requires that subjects stand up from a chair, walk 10 ft, turn around, and return. The time to complete the activity is recorded. . A second trial will be performed with the subject performing a cognitive task (i.e. subtracting by 3s or spelling words) while walking. A safety belt will be used when performing the assessment. Time to complete is 1 minute. This is an objective measure of balance in an activity of daily function. GAITRite electronic walkway may be used if available to allow the researchers to gather greater data on subjects walking during the above 10 meter walk.
 5. Four-Test Balance Scale (FTBS) -This is a balance test that progressively challenging. The test is stop if the person is unable to perform task for the required amount of time. Intially, the subject is asked to stand with feet together for 10 seconds with eyes open; if able to perform this activity the subject is then asked to stand in a semi-tandem position (feet touching but one foot slightly ahead of the other) for 10 sec; if able to do so, the subject then is asked to perform a tandem stand (heel to toe) for 10 sec; if able to do so, the subject will be progressed to one leg stand for up to 30 seconds. If subject is unable to stand for 30 sec, time of trial will be recorded. A safety belt will be used during this assessment. Time to complete is 3-5 minutes. This is an objective measure of balance and strength.
 6. Fall and Activity Survey and Stepping On Participation Evaluation - each subject will be given a survey following the completion of Stepping On sessions at Week 7, at 3-month Booster session and at the 6 months recheck to record any falls that have occurred and to monitor follow through of assigned strength and balance exercises. Fall is defined as an event that results in a person unintentionally coming to rest on the ground, floor, or other lower level. (Buchner) If a subject is unable to attend the Booster session and/or at the 6-month recheck they will be contacted by phone or mail in regards to the survey
- e) Describe audio/visual procedures and proper disposal of tapes.
NA
- f) Describe the qualifications of the individuals conducting all procedures used in the study.
Meridee Danks has been a practicing physical therapist for 28 years and has a speciality certification in Neurologic Physical Therapy. Bev Johnson has been a practicing physical therapist for 30+ years and has Doctoral of Science in Geriatrics. UND-PT students will be supervised & trained as needed.
- g) Describe compensation procedures (payment or class credit for the subjects, etc.).
NA

Revised 04/02/12

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

3. Risk Identification.

- a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.
There is a minimal risk of loss of balance with the balance assessments (TUG/FTBS/etc). Each of these test will be performed with a safety belt and spotter to prevent any falls. The subject will be instructed that they can quit the activity at any time if they do not feel safe performing it.
- b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.
There will be a link to each subject in order to compare to survey information at recheck times. Once all the data (after 6-month recheck) is collected the link will be destroyed.
- c) Provide a description of the data monitoring plan for all research that involves greater than minimal risk.
NA
- d) If the PI will be the lead-investigator for a multi-center study, or if the PI's organization will be the lead site in a multi-center study, include information about the management of information obtained in multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications.
NA

4. Subject Protection.

- a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).
A safety belt and spotter will be used during each balance assessment. Subjects will be informed that they can stop any activity that they do not feel safe performing.
- b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.
All data will be coded and identifying information removed once all data is gathered. Any reporting will be in aggregate form. The assessments will be performed in a private room. Follow-up survey's will be sent back to researcher with ID number only.
- c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.
Each subject will be provided with a copy of the consent form.
- d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.
Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)
2) who will have access to the data
3) how the data will be destroyed
4) the storage location of consent forms and personal data (separate from research data)
5) how the consent forms will be destroyed
 1. The research data will be stored separately from the consent form and other personal data.
 2. Only the researchers will have access to the data.
 3. The data will be kept a minimum of 3 years and will be shredded once data analysis is completed.
 4. Consent forms/personal data and data will be stored in separate files in the locked office of the researcher.
 5. The consent forms will be kept a minimum of 3 years and then will be shredded.

- e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.). Referrals will be made to family physician if subjects have concerns regarding their balance.
- f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.
Subject will be referred for medical treatment if required for any injury that may occur during assessment. The responsibility of cost related to any treatment will be the responsibility of the subject.

III. Benefits of the Study

Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). **Please note:** extra credit and/or payment are not benefits and should be listed in the Protocol Description section under Methodology.

Subjects will be able to have their balance assessed at no cost. They will be able to see if there was any benefit of attending Stepping On program. General benefit to society to see how effective a preventative balance program can be.

IV. Consent Form

Clearly describe the consent process below and be sure to include the following information in your description (Note: Simply stating 'see attached consent form' is not sufficient. The items listed below must be addressed on this form.):

- 1) The person who will conduct the consent interview
 - 2) The person who will provide consent or permission
 - 3) Any waiting period between informing the prospective participant and obtaining consent
 - 4) Steps taken to minimize the possibility of coercion or undue influence
 - 5) The language to be used by those obtaining consent
 - 6) The language understood by the prospective participant or the legally authorized representative
 - 7) The information to be communicated to the prospective participant or the legally authorized representative
- 1. Meridee Danks and Bev Johnson will conduct the consent interview.
 - 2. Researchers listed above will provide the consent forms.
 - 3. No waiting period.
 - 4. Prospective subjects will be told that research is voluntary and that if they do decide to participate that they are able to stop at any time without any penalty.
 - 5. English
 - 6. English
 - 7. The consent form will indicate the assessments to be performed and the amount of time to perform them and who will be performing the assessments.

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects, and complete the Application for Waiver or Alteration of Informed Consent Requirements. Refer to form IC 701-A, Informed Consent Checklist, and make sure that all the required elements are included. **Please note:** All records attained must be retained for a period of time sufficient to meet federal, state, and local regulations; sponsor requirements; and organizational policies. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. **The consent form should be written at no higher than an 8th grade reading level**, and it is recommended that it be written in the third person (please see the example on the RD&C website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp.

Necessary attachments:

- ☐ Signed Student Consent to Release of Educational Record Form (students only);
- ☒ Investigator Letter of Assurance of Compliance;
- ☒ Consent form, or Waiver or Alteration of Informed Consent Requirements (Form IC 702-B)
- ☒ Surveys, interview questions, etc. (if applicable);
- ☐ Printed web screens (if survey is over the Internet); and

☐ Advertisements.

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signature: _____

(Principal Investigator)

Date: 3/6/15

(Student Adviser)

Date: _____

Requirements for submitting proposals:

Additional information can be found on the IRB web site at: <http://und.edu/research/research-economic-development/institutional-review-board/>.

Original Proposals and all attachments should be submitted to: Institutional Review Board, 264 Centennial Drive Stop 7134, Grand Forks, ND 58202-7134, or brought to Room 106, Twamley Hall.

Prior to receiving IRB approval, researchers must complete the required IRB human subjects' education. Please go to: <http://und.edu/research/research-economic-development/institutional-review-board/human-subject-education.cfm>

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the IRB website regarding required copies and IRB review categories, or you may call the IRB office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 5 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 5 copies of the company's protocol must be provided.

APPENDIX C

Stepping On Workshop Participant Evaluation

Workshop Site: _____ Today's Date: _____

Please help us to make improvements to the design of the *Stepping On* program by completing this evaluation and returning it to one of the Leaders. Thank you.

1. What is your age? _____
2. What is your gender?
☐ Male
☐ Female
3. What is your race?
☐ American Indian or Alaska Native
☐ Asian or Asian-American
☐ Black or African-American
☐ Hawaiian Native or Pacific Islander
☐ Hispanic
☐ White or Caucasian
☐ Other: _____
4. What is your current marital status? (Check only one.)
☐ Married
☐ Divorced
☐ Widowed
☐ Separated
☐ Never married
☐ Partnered (living with someone)
5. Have you fallen within the last year?
☐ No
☐ Yes
If yes, what was the cause of the fall? _____
6. How many people live in your household (including yourself)? _____
7. What is your location of residence?
☐ Rural/countryside
☐ Small town
☐ City/suburb of a city

Place an X in the box to indicate your response.

	Nothing	←	Some	→	Alot
8. Overall, how much did you learn from these sessions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please rate your level of knowledge on each of the following:

	Low	←	Moderate	→	High
--	-----	---	----------	---	------

9. My understanding of how vision can influence the ability to get around safely.

Before Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Now, After Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. My understanding of the importance of balance and strength exercises for preventing falls.

Before Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Now, After Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. My knowledge of recognizing hazards in home environments.

Before Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Now, After Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. My understanding of the relation between safe footwear and fall prevention.

Before Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Now, After Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. My confidence in applying safe strategies in mobility situations.

Before Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Now, After Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

14. My understanding of the relation between medications and falls.

Before Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Now, After Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

15. My knowledge of the importance of good bone health and fall prevention.

Before Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Now, After Participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

16. Which of your behaviors are you most likely to change?

17. List the three most important things you learned in this workshop.

a.

b.

c.

18. Which topic was least interesting?

19. Other comments concerning the workshop

Fall Risk Survey

ID # _____ Age: _____ Gender: ☐ Male ☐ Female Date: _____

Fall Risk Factor	Factor Present	Notes
Any falls in the last year?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, how many?
Do you use an assistive device? (Cane, Walker, etc.)	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, what kind?
Do you worry about falling when standing or walking?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Do you spend less than 30 minutes per day 5-7 days per week being physically active?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Do you take more than 4 prescription medications?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Has it been longer than 1 year since your last vision check?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Do you have vision impairments? (glasses, macular degeneration, glaucoma, etc.)	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, what kind?
Have you had any surgeries in the last year? (Hip, Knee, etc.)	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, what kind?
Do you have any heart rate or rhythm issues?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Do you have any sensation loss to your legs or feet?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Are you depressed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Yes TOTAL:		

The Activities-specific Balance Confidence (ABC) Scale*

Instructions to Participants:

For each of the following, please indicate your level of confidence in doing the activity without losing your balance or becoming unsteady from choosing one of the percentage points on the scale from 0% to 100%. If you do not currently do the activity in question, try and imagine how confident you would be if you had to do the activity. If you normally use a walking aid to do the activity or hold onto someone, rate your confidence as it you were using these supports. If you have any questions about answering any of these items, please ask the administrator.

The Activities-specific Balance Confidence (ABC) Scale*

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale:

0% 10 20 30 40 50 60 70 80 90 100%
no confidence completely confident

“How confident are you that you will not lose your balance or become unsteady when you...

1. ...walk around the house? _____%
2. ...walk up or down stairs? _____%
3. ...bend over and pick up a slipper from the front of a closet floor _____%
4. ...reach for a small can off a shelf at eye level? _____%
5. ...stand on your tiptoes and reach for something above your head? _____%
6. ...stand on a chair and reach for something? _____%
7. ...sweep the floor? _____%
8. ...walk outside the house to a car parked in the driveway? _____%
9. ...get into or out of a car? _____%
10. ...walk across a parking lot to the mall? _____%
11. ...walk up or down a ramp? _____%
12. ...walk in a crowded mall where people rapidly walk past you? _____%
13. ...are bumped into by people as you walk through the mall? _____%
14. ...step onto or off an escalator while you are holding onto a railing?
_____%
15. ...step onto or off an escalator while holding onto parcels such that you
cannot hold onto the railing? _____%
16. ...walk outside on icy sidewalks? _____%

*Powell, LE & Myers AM. The Activities-specific Balance Confidence (ABC) Scale. *J Gerontol Med Sci* 1995; 50(1): M28-34

Date _____

ID # _____

Stepping On Survey – Week 7

1. Do you feel your balance and confidence have improved while performing daily activities as a result of participating in the Stepping On Program?

Balance Yes _____ No _____

Confidence Yes _____ No _____

If yes, what information helped you the most?

2. A fall is any event that led to an unplanned, unexpected contact with a supporting surface such as the floor. Have you fallen since starting the Stepping On Program?

Yes _____ No _____ If yes, how many falls since the program began: _____

Describe the cause of fall(s) and any injuries that occurred:

3. How would you rate your present level of daily physical activity? (circle one)

Inactive/Low

Moderate

High

If your physical activity is limited, what do you think is the major reason?

4. Have you performed the Stepping On exercises faithfully?

Yes _____ No _____

If no, what has kept you from performing the exercises as per the recommended amount of times?

If yes, record on the chart below how often each week you perform the Stepping On exercises, the number of repetitions you do of each exercise, and the amount of weight you use with the strength exercises?

Balance Exercises:

	# times/week	# of repetitions
Sit-to-Stand		
Sideways Walking		
Heel-toe standing		
Heel-toe walking		

Strength Exercises:

	# times/week	# of reps & weight
Side-hip-strengthening		
Knee-strengthening		
Heel raises		
Toe raises		

5. Do you have any difficulties performing the above exercises?

Yes _____ No _____ If yes, describe what difficulties you are having?

6. Had you been actively exercising at home prior to the Stepping On program?

Yes _____ No _____ If yes, what type of exercise did this include?

How frequently do you perform these? _____

7. Do you participate in community exercise groups (other than Stepping On program)?

Yes _____ No _____ If yes, what group and/or type of exercise?

How often do you attend? _____

Date _____

ID # _____

Stepping On Survey – 3 months after

1. Do you feel your balance and confidence have improved while performing daily activities as a result of participating in the Stepping On Program?

Balance Yes___ No___

Confidence Yes___ No___ If yes, what strategies have helped you?

2. Do you feel that the Stepping On Program has helped you?

Yes___ No___ If yes, how has it helped you?

3. Have you had any falls since completing the Stepping On Program?

Yes___ No___ If yes, how many falls: _____
What was the cause(s) of the fall(s)?

4. How often do you perform the Stepping On exercises usually? (Circle below)

Strength: $\geq 3x/\text{week}$ 2x/week 1x/week < than 1x/week Not at all

Balance: $\geq 3x/\text{week}$ 2x/week 1x/week < than 1x/week Not at all

If you have not been doing the exercises regularly, what has kept you from doing so?

5. Have you joined or continued any community exercise groups since the Program?

Yes___ No___ If yes, what group?

APPENDIX D

Tested on: 10/5/2015 11:06:49 AM

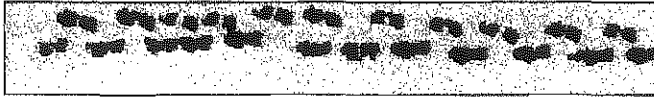
UND-PT

501 North Columbia Rd

Tel# 7017773861

Grand Forks ND 58202-9037

Age	Gender	Left	LEG	Right	Height	Weight
81	F	0		0	167.64	0



Parameters

Distance (cm)	386.8	Cadence (Steps/Min)	57.9
Ambulation Time (sec)	22.81	Step Time Differential (sec)	.09
Velocity (cm/sec)	17.0	Step Length Differential (cm)	2.24
Mean Normalized Velocity	.00	Cycle Time Differential (sec)	.02

Walk # / Footfall #	L/R	Mean(%CV)	1	2	3	4	5	6	7	8	9	10	11	12	13
Step Time (sec)	L	992(33.0)			1.014		.947		.914		1.229		1.429		715
	R	1.081(33.0)		.997		.847		1.013		.931		1.811		.797	
Cycle Time (sec)	L	2.074(30.0)			2.011		1.794		1.927		2.160		3.240		1.512
	R	2.092(30.0)				1.861		1.960		1.845		3.040		2.226	
Swing Time (sec)	L	.347(61.0) /16.7			.366		.349		.415		.365		.249		.100
	/ %GC	R .618(60.0) /29.5				.581		.764		.486		1.578		.498	
Stance (sec)	L	1.729(31.0) /83.2	1.645		1.445		1.512		1.795		2.991		1.412		1.296
	/ %GC	R 1.474(17.0) /70.5		1.280		1.198		1.379		1.462		1.728		1.263	
Single Support (sec)	L	.618(60.0) /29.8			.581		.764		.486		1.578		.498		.266
	/ %GC	R .347(61.0) /16.6		.366		.349		.415		.365		.249		.100	
Double Support (sec)	L	1.117(33.0) /53.9			.864		.748		1.329		1.413		.914		1.030
	/ %GC	R 1.134(22.0) /54.2		.914		.847		.964		1.097		1.479		1.163	
Step Length (cm)	L	16.460(31.0)			17.090		20.579		20.054		22.590		16.269		6.175
	R	18.701(23.0)		15.963		19.214		20.798		15.510		15.751		25.080	
Stride Length (cm)	L	35.245(20.0)			33.107		39.877		40.866		38.278		33.027		31.255
	R	35.479(15.0)				36.304		41.388		35.850		39.688		41.349	
Base of Support (cm)	L	14.38(18.0)			13.967		10.863		13.735		14.922		18.208		19.244
	R	14.28(17.0)		13.281		12.629		10.931		14.148		17.898		18.093	
Toe In / Out (deg)	L	4(.0)			-2		4		9		10		3		3
	R	13(.0)		15		11		19		9		14		13	

normal walking no AD

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